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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,281	10/13/2000	Hyun Kim	GI 5387	9127

7590 05/23/2002

American Home Products Corporation
Attn Kay E Brady
Patent & Trademark Office 2B
One Campus Drive
Parsippany, NJ 07054

EXAMINER

WEBER, JON P

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application N .

09/687,281

Applicant(s)

KIM ET AL.

Examiner

Jon P. Weber, Ph.D.

Art Unit

1651

--The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 10 May 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: new claim, new rejection, no improvement.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-7.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

Jon P. Weber, Ph.D.
Primary Examiner
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Status of the Claims

The response with amendments after Final filed 10 May 2002 has been received but the amendments have **not** been entered. Claims 1-7 remain presented for examination.

Claim Rejections - 35 USC § 112

Claims 1-7 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The response argues that “derivative” and “pore-forming agent” would be understood by a person of ordinary skill in the art and are defined in the disclosure.

Claims are given their broadest reasonable interpretation. While the term “derivative” is commonly used in the art, it does not have a set or clear meaning. Derivatives can be as simple as salts and esters or as complex as conjugates or degradation products. Similarly, “pore-forming agent” is a very broad term. For example, well known “pore-forming agents” are gramicidin and electroporation or sonoporation. These range from chemical to physical. The metes and bounds of the claim terminology are unclear. While claims must be "given the broadest reasonable interpretation consistent with the specification", "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from 'reading limitations of the specification into a claim,' to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim." *In re Prater* , 162 USPQ 541, 550 -51 (CCPA 1969). This is impermissible importation of subject matter from the specification into the claim.

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Applicant's arguments filed 10 May 2002 have been fully considered but they are not persuasive. The rejection under 35 USC 112, second paragraph is adhered to for the reasons of record and the additional reasons above.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4 and 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Vanis et al. (CZ 283073).

The response argues that Kubler et al. (sic – presumably Vanis et al.) does not anticipate the claimed invention because it contains calcium phosphate and/or fluorophosphates. It is stated that applicants have discovered that tricalcium phosphate in the formulation increases retention of BMP at the site of injection thereby accelerating fracture repair. Finally it is concluded that applicants claim an injectable composition comprising osteogenic protein and hyaluronic acid.

The composition of Vanis et al. comprises calcium phosphate, hyaluronic acid and BMP in admixture with physiological fluids. This composition may be formed into desired shapes. It is deemed that the composition which is in paste form is injectable in the same way that such materials are injected like icing through a pastry bag, caulk through a caulk gun, or even plastics via injection molding. The instant claims use the open permissive language “comprising” which encompasses other ingredients. Further, the limitation “injectable” is inherently met by the pasty composition produced.

Applicant's arguments filed 10 May 2002 have been fully considered but they are not persuasive. The rejection under 35 USC 102(b) is adhered to for the reasons of record and the additional reasons above.

Claim Rejections - 35 USC § 103

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wozney et al. (US 6,187,742).

It is argued that Wozney et al. only list the ingredients in multiple laundry lists encompassing many options and do not provide motivation to pick and choose from among these to obtain the claimed invention.

The mere fact that Wozney et al. disclose these components in the alternative is motivation enough. The members of each list are considered to be functional equivalents of each other. It is thought by Wozney et al. that any combination from the various lists would provide a functional composition.

Claims 1-2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee et al. (US 5,752,974).

Claims 1-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. (US 5,939,323).

It is argued that neither Rhee et al. nor Valentini et al. disclose their compositions for the same intended use as the instantly claimed invention.

A rejection under 35 U.S.C. § 103 based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention. *Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417. That Rhee et al. and Valentini et al. disclose their

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composition for a different intended use is not probative. Rhee et al. and Valentini et al. both provide motivation to form the same composition as that claimed.

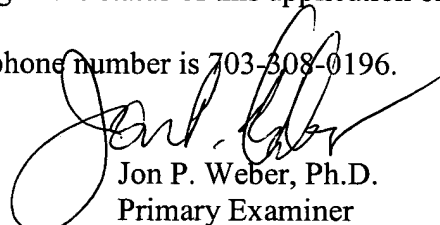
Applicant's arguments filed 10 May 2002 have been fully considered but they are not persuasive. The rejections under 35 USC 103 are adhered to for the reasons of record and the additional reasons above.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P. Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P. Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
May 21, 2002